**MATERIAL TRANSFER AGREEMENT**

The NCI-supported Pediatric Preclinical Testing Program (PPTP) is a comprehensive program to systematically evaluate new agents against childhood solid tumor and leukemia models. The PPTP is supported through a National Cancer Institute (NCI) research contract to the Research Institute at Nationwide Children's Hospital (NCH) with Dr. Peter Houghton as the Principal Investigator. Testing and data analysis occur both at NCH and also at subcontract sites that have expertise in specific childhood cancers, including: Children’s Hospital of Philadelphia (John Maris), Albert Einstein Medical Center (Richard Gorlick), Duke University (Henry Friedman), Texas Tech University Health Sciences Center (C. Patrick Reynolds), Children’s Cancer Institute Australia (Richard Lock), and St. Jude Children’s Research Hospital (Jianrong Wu). The primary goal of the PPTP is to identify new agents that have the potential for significant activity when clinically evaluated against selected childhood cancers.

Collaborator:\_\_\_\_\_\_\_\_\_

NCI: National Cancer Institute, Division of Cancer Treatment and Diagnosis

1. Collaborator agrees to transfer to NCI the following Research Material, which is proprietary and confidential to Collaborator for use in the Pediatric Preclinical Testing Program (PPTP): an initial supply of \_\_\_\_\_\_. Neither the identity of Collaborator nor the Research Material will be provided to investigators participating in the PPTP (“PPTP Investigators”) until NCI determines that such disclosure is appropriate.

2. THE RESEARCH MATERIAL MAY NOT BE USED IN HUMANS. The Research Material will not be used (i) for commercial purposes, including for screening, production or sale, for which a commercialization license may be required or (ii) in any research in which a for-profit company (other than Collaborator) has rights or an option to obtain rights, including the right to obtain access to data or results. NCI and the institutions of PPTP Investigators (“Institutions”) that receive Research Material from NCI under this Agreement agree to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material. All Institutions participating in the PPTP have signed Material Transfer Agreements (MTAs) (web site: <http://ctep.cancer.gov/industry>) with the NCI for the transmittal of Collaborator’s Research Material to Institutions. Said MTAs with Institutions include the “Intellectual Property Option to Collaborator” offering Collaborator first rights of negotiation to Institutions inventions, and publication provisions consistent with the terms and obligations of this Agreement.

3. The Research Material will be provided for use by PPTP Investigators solely in connection with the following research project ("Research Project") described with specificity as follows (use an attachment page if necessary). Results of the Research Project shall be provided exclusively and in confidence to the NCI and the PPTP Steering Committee (NCI staff and selected childhood cancer experts who advise NCI staff concerning the agents evaluated by the PPTP).

This Research Material will be used for preclinical studies to evaluate the Research Material against panels of pediatric tumors comprised of neuroblastoma, brain tumors, osteosarcoma, soft tissue sarcomas, Ewing family tumors, Wilms tumor, Rhabdoid tumor and models of acute lymphoblastic leukemia, in SCID or athymic nude mice. The *in vivo* primary screen comprises various tumor models and represents many of the cancer types that occur in children. Additional studies will determine the sensitivity *in vitro* of cell lines representing many of these same tumor types.

 4. Neither NCI, Institution, Institutions’ PPTP Investigators, nor other Institution employees or agents who have access to Research Material from NCI under this Agreement shall (a) make any complements, analogs, conjugates, derivatives or modifications of the Research Material or (b) sequence, analyze, or otherwise determine the chemical structure or physical properties of the Research Material, to the extent such structure or properties are not already publicly known or expressly provided for in the Research Project description; and if Institution, Institution’s PPTP Investigator, or Institution employee or agent does so in violation of the foregoing, then Institution hereby agrees that all such complements, analogs, conjugates, derivatives, modifications, and sequences are Collaborator Inventions as defined in the Intellectual Property Option to Collaborator provision of NCI’s MTA with Institution, and shall be treated in accordance with the provisions of that section.

5. The Research Material is proprietary and confidential to Collaborator. Collaborator has agreed to allow NCI to make its proprietary compound available to Institutions’ PPTP Investigators solely for use in furtherance of this Research Project. No license grant to or assignment of interest in the Research Material, express or implied, by estoppel or otherwise is intended or shall be construed by Collaborator’s agreement to provide Research Material for the Research Project. NCI may distribute the Research Material only to PPTP Investigators at Institutions who have signed MTAs with the NCI consistent with the terms of this Agreement and solely for use in furtherance of the Research Project. When the Research Project is completed, NCI will oversee the lawful disposal of the Research Material by the Institution’s PPTP Investigator (with certification of such destruction provided to Collaborator), unless directed otherwise by Collaborator.

6. The Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO NCI BY THE COLLABORATOR AND THEREAFTER BY NCI TO INSTITUTIONS WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Collaborator makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. Collaborator agrees to hold NCI and Institutions harmless and to indemnify NCI and Institutions for all liabilities, demands, damages, expenses and losses arising out of Collaborator’s use for any purpose of the data resulting from the Research Project. NCI, as an agency of the United States, assumes responsibility for any liabilities, damages, losses and costs incurred in connection with NCI’s use, handling, storage, transfer, or disposal of the Research Material only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. Ch. 171.

7. NCI agrees to provide Collaborator with updates of the Research Project using the Research Material periodically and will inform Collaborator promptly of any significant results that arise from such Research Project. NCI will also provide Collaborator a report of the final results at the completion of the Research Project. NCI agrees that, subject to the publication rights under Section 10 of this Agreement, it shall keep the research results confidential until the results are published by the NCI and PPTP Institutions in accordance with Section 11 of this Agreement, and that Collaborator and its affiliates and agents are hereby granted the right to use, without further consideration, all data and results generated under this Research Project for any lawful purpose, including for Collaborator’s own analyses and for use in regulatory or intellectual property filings.

8. The undersigned Collaborator and NCI expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

9. This Agreement shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

 10. The following will apply to all publications or presentations at the appropriate time for such disclosures. In all oral presentations or written publications concerning the Research Project, PPTP Investigators will acknowledge Collaborator’s contribution of the Research Material unless requested otherwise. To the extent permitted by law, NCI agrees to treat in confidence, for a period of five (5) years from the date of its disclosure, any of Collaborator’s written information about the Research Material that is/are stamped "CONFIDENTIAL" (“Confidential Information”), except for information that NCI can clearly demonstrate by competent written proof was previously known to NCI or that is or becomes publicly available without breach of this Agreement by NCI or which is disclosed to NCI without a confidentiality obligation by a third party having a lawful right to do so. For the avoidance of any doubt, the identity or identification of the Research Material, any non-public code number or designation associated with the Research Material and any link between the Research Material as identified in the Research Project and the Research Material as it may otherwise be known or identified shall all constitute Confidential Information of the Collaborator. Any oral disclosures from Collaborator to NCI of Confidential Information shall be summarized in writing within thirty (30) days after the date of the oral disclosure. All Confidential Information shall be used solely in furtherance of the Research Project and not for any other purpose.

 11. Collaborator agrees that NCI may publish the data and results generated under the Research Project in peer-reviewed scientific journals or present those data and results at academic symposia or similar professional meetings in accordance with the following provisions. Such public disclosure may be made only after Collaborator has had forty-five (45) days to review the proposed disclosure to determine if it includes any Confidential Information or patentable invention, except when a shortened time period under court order or the Freedom of Information Act pertains. To ensure Collaborator’s review of proposed disclosure, NCI will provide a copy of the proposed disclosure to Collaborator not less than forty-five (45) days prior to submission of a paper for publication and not less than seven (7) days prior to submission of an abstract for publication.

12. This Agreement constitutes the entire agreement and understanding of the parties and supersedes any prior agreements, promises or understandings, written or verbal, relating to the subject matter hereof. This Agreement may not be changed or supplemented, nor may any provision or the benefit thereof be waived, except by a writing duly signed by all parties.

13. Each party represents to the other that (a) it has the full power and authority, and has taken all necessary actions and has obtained all necessary authorizations, licenses, consents and approvals required, to execute and perform this Agreement, (b) is not bound by or subject to any law that would conflict with, prohibit or interfere with the performance of its obligations hereunder, and (c) neither party is nor shall become party during the term of this Agreement to any agreement, arrangement, joint venture, collaboration, competitive project, or other dealing whatsoever with any other person or body that would or might affect, conflict with or prejudice this Agreement or the rights of either party under it.

14. This Agreement shall terminate three (3) years from the date of the final signature. The second sentence of Section 7 and the third sentence of Section 10 shall survive the termination for the period provided therein.

**Signatures Begin on the Next PageSIGNATURES**

## COLLABORATOR

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Authorized Signature for Collaborator and Title

Collaborator’s Mailing Address:

(please provide info)

**NATIONAL CANCER INSTITUTE**

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Date Thomas P. Clouse, J.D., M.F.S., CLP

Technology Transfer Specialist

Technology Transfer Center, NCI

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Sherry Ansher, Ph.D.

 Associate Chief, Research and Development Agreements

Please address all correspondence related to this agreement to Dr. Zhang at the following address:

Jianqiao Zhang, Ph.D.

Regulatory Affairs Branch

Cancer Therapy Evaluation Program

DCTD, NCI, NIH

9609 Medical Center Dr., Rm. 5-W534

Rockville, MD 20850 (Fed Ex only)

(240) 276-6580 tel.

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801‑3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).